IRB: _____
Protocol #: _____
Date: _____
Reviewer: _____

Additional DHHS Protections Pertaining to Research Involving Pregnant Women, Human Fetuses and Neonates

The purpose of this checklist is to aid you in your evaluation of CDC research involving pregnant women, human fetuses and neonates. In addition to the responsibilities of the IRB under Subpart A, the IRB shall carry out the following ***additional protections*** when research involves pregnant women, human fetuses and neonates. However, if pregnant women, human fetuses and neonates are ***NOT*** the target of the research, Subpart B does not apply.

Minimal Risk

The Federal Regulations divide research into that which is minimal or not greater than minimal risk to the participant and that which is greater than minimal risk. The definition of minimal risk given in §46.102(i) reads as follows:

"Minimal risk means that the ***probability*** and ***magnitude*** of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests."

Level of Risk for this protocol (please insert "minimal" or "greater than minimal"):

_____

Please use the following determination key when evaluating research involving pregnant women, human fetuses and neonates to ensure that the ***additional protection*** has been satisfactorily addressed:

Y = adequately addressed in protocol
M = missing in protocol
I = incomplete or problematic in protocol

Research involving pregnant women or fetuses (Sec. 46.204). Pregnant women or fetuses may be involved in research if **ALL** of the following conditions are met:

Additional Protection	Notes
(a) Where scientifically appropriate, preclinical studies, including studies on pregnant animals, and clinical studies, including studies on nonpregnant women, have been conducted and provide data for assessing potential risks to pregnant women and fetuses;	
(b) The risk to the fetus is caused solely by interventions or procedures that hold out the prospect of direct benefit for the woman or the fetus; or, if there is no such prospect of benefit, the risk to the fetus is not greater than minimal and the purpose of the research is the development of important biomedical knowledge which cannot be obtained by any other means;	
(c) Any risk is the least possible for achieving the objectives of the research;	
(d) If the research holds out the prospect of direct benefit to the pregnant woman, the prospect of a direct benefit both to the pregnant woman and the fetus, or no prospect of benefit for the woman nor the fetus when risk to the fetus is not greater than minimal and the purpose of the research is the development of important biomedical knowledge that cannot be obtained by any other means, her consent is obtained in accord with the informed consent provisions of subpart A of this part;	
(e) If the research holds out the prospect of direct benefit solely to the fetus then the consent of the pregnant woman and the father is obtained in accord with the informed consent provisions of subpart A of this part, except that the father's consent need not be obtained if he is unable to consent because of unavailability, incompetence, or temporary incapacity or the pregnancy resulted from rape or incest.	
(f) Each individual providing consent under paragraph (d) or (e) of this section is fully informed regarding the reasonably foreseeable impact of the research on the fetus or neonate;	
(g) For children as defined in Sec. 46.402(a) who are pregnant, assent and permission are obtained in accord with the provisions of subpart D of this part;	
(h) No inducements, monetary or otherwise, will be offered to terminate a pregnancy;	
(i) Individuals engaged in the research will have no part in any decisions as to the timing, method, or procedures used to terminate a pregnancy; and	
(j) Individuals engaged in the research will have no part in determining the viability of a neonate.	

Research involving neonates (Sec. 46.205):

Additional Protection	Notes
(a) Neonates of uncertain viability and nonviable neonates may be involved in research if **ALL** of the following conditions are met:	
(1) Where scientifically appropriate, preclinical and clinical studies have been conducted and provide data for assessing potential risks to neonates.	1
(2) Each individual providing consent under paragraph (b)(2) or (c)(5) of this section is fully informed regarding the reasonably foreseeable impact of the research on the neonate	2
(3) Individuals engaged in the research will have no part in determining the viability of a neonate.	3
(4) The requirements of paragraph (b) or (c) of this section have been met as applicable.	4
(b) Neonates of uncertain viability. Until it has been ascertained whether or not a neonate is viable, a neonate may not be involved in research covered by this subpart unless the following additional conditions are met:	
(1) The IRB determines that: (i) The research holds out the prospect of enhancing the probability of survival of the neonate to the point of viability, and any risk is the least possible for achieving that objective, or	1(i)
(ii) The purpose of the research is the development of important biomedical knowledge which cannot be obtained by other means and there will be no added risk to the neonate resulting from the research; and	1(ii)
(2) The legally effective informed consent of either parent of the neonate or, if neither parent is able to consent because of unavailability, incompetence, or temporary incapacity, the legally effective informed consent of either parent's legally authorized representative is obtained in accord with subpart A of this part, except that the consent of the father or his legally authorized representative need not be obtained if the pregnancy resulted from rape or incest.	2
(c) Nonviable neonates. After delivery nonviable neonate may not be involved in research covered by this subpart unless all of the following additional conditions are met:	
(1) Vital functions of the neonate will not be artificially maintained;	1
(2) The research will not terminate the heartbeat or respiration of the neonate;	2
(3) There will be no added risk to the neonate resulting from the research;	3
(4) The purpose of the research is the development of important biomedical knowledge that cannot be obtained by other means; and	4

(5) The legally effective informed consent of both parents of the neonate is obtained in accord with subpart A of this part, except that the waiver and alteration provisions of Sec. 46.116(c) and (d) do not apply. However, if either parent is unable to consent because of unavailability, incompetence, or temporary incapacity, the informed consent of one parent of a nonviable neonate will suffice to meet the requirements of this paragraph (c)(5), except that the consent of the father need not be obtained if the pregnancy resulted from rape or incest. The consent of a legally authorized representative of either or both of the parents of a nonviable neonate will not suffice to meet the requirements of this paragraph (c)(5).	5
(d) Viable neonates. A neonate, after delivery, that has been determined to be viable may be included in research only to the extent permitted by and in accord with the requirements of subparts A and D of this part.	

Research involving, after delivery, the placenta, the dead fetus or fetal material (Sec 46.206):

Additional Protection	45 CFR 46.206	Notes
(a) Research involving, after delivery, the placenta; the dead fetus; macerated fetal material; or cells, tissue, or organs excised from a dead fetus, shall be conducted only in accord with any applicable Federal, State, or local laws and regulations regarding such activities.		
(b) If information associated with material described in paragraph (a) of this section is recorded for research purposes in a manner that living individuals can be identified, directly or through identifiers linked to those individuals, those individuals are research subjects and all pertinent subparts of this part are applicable.		

Research not otherwise approvable which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of pregnant women, fetuses, or neonates (Sec. 46.207):

Additional Protection	Notes
Research not otherwise approvable which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of pregnant women, fetuses, or neonates.	